

REMARKS

Applicants have reviewed the Office Action mailed June 24, 2009. Claims 1, 36, and 37 are amended. Claim 11 is cancelled. New claim 38 is added. Claims 1, 4-8, 10, and 12-38 are pending. Applicants request reconsideration.

Claims 1, 7, 12-17, 19-24, 27-30, and 35-37 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Ebert (GB 2151201) in view of Monte (U.S. Patent No. 5,578,336) and Brox (U.S. Patent No. 4,780,316).

Claims 1, 4-7, 11, 12, 15-17, 19-30, and 35-37 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Ebert in view of Cavanak (U.S. Patent No. 5,639,724) and Brox.

Claims 1, 4-7, 11, 12, 15-17, 19, 20, 22, 24-30, and 35-37 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Lech (U.S. Patent No. 6,027,746) in view of Cavanak.

These three rejections are traversed together.

The issue between Applicants and the Examiner appears to be clear. The Examiner's reasoning has relied on storage for extended periods of time as disclosing the aging step of the present claims. Applicants amended the claims to recite drying for a period of 5 to 64 hours.

On page 8 of the Response to Arguments, the Examiner noted that Brox taught a storage condition at zero month. The Examiner also shifted the burden to Applicants to show that Lech's disclosure of "extended periods" indeed indicated a minimum storage period of one month.

With regards to Brox, the Examiner's reasoning relied on the time of storage to correspond to the aging time. Applicants submit that Brox's storage condition of zero months is equivalent to no drying/aging at all, i.e. a time of zero hours, which is outside the claimed floor of 5 hours. The Examiner's new reasoning is now below the claimed range of 5 to 64 hours. Thus, a storage time of zero hours will not render the present claims obvious. In addition, please note that Brox's examples require a starting

reference point, i.e. zero months, to measure changes in properties over time. It would be unreasonable for the Examiner to equate zero months to any sort of aging.

With regards to Lech, Applicants first reject the assertion that it is Applicants' burden to prove the meaning of Lech's ambiguous phrase. Rather, it is the Examiner's burden to show that "extended periods" refers to a time period that renders obvious the claimed drying / aging time of 5-64 hours, as claimed.

In addition, Applicants did not state that Lech itself indicated a minimum storage period of one month. Lech does not teach any minimum storage period. In addition, all that Lech states is that the capsules were stable, and that stability is with relation to the drug, not the actual properties of the capsule. There is no discussion of the ingestion properties of the capsules at all.

Applicants submit that U.S. Patent No. 6,071,523 to Mehta, previously cited by the Examiner, provides a reasonable basis for construing the "extended periods" of Lech to be longer than the claimed 64 hours. In column 2, lines 27-33, Mehta states that three months storage at a temperature of at least about 40°C at 75% humidity extrapolates to two years shelf-life stability at room temperature under assumptions accepted by the U.S. Food and Drug Administration. Both Lech and Mehta are directed towards pharmaceutical compositions, so would reasonably have the same stability requirements and the same need to test for shelf-life. Lech tests at 30°C, 40°C, and 50°C, which reasonably surround the 40°C test described by Mehta. Although Lech does not state his humidity, Applicants submit that Mehta provides a basis for reasonably assuming that Lech's "extended periods" refers to a time period longer than the claimed 64 hours.

On page 9 of the Response to Arguments, the Examiner stated that arguments regarding Type V and Type VI crystals were not recited in the rejected claims. Applicants do not agree with this reasoning, as the claims are read in light of the specification and it is clear that such crystals are present in the already-recited cacao butter. In addition, Ebert, Brox, and Lech are not directed to the use of cacao butter. This point should be considered because the aging time/temperature relates to the fill material to be aged.

To expedite prosecution, Applicants have amended the independent claims to recite these elements. Support is found on page 20, line 10 to page 21, line 15; page 36, line 17 to page 38, line 5 (describing Production Examples 29 and 30); and Figures 2 and 3.

Applicants note that the value "no greater than 4.7 kgs" in new claim 38 was determined by extrapolation from Figure 3. If the Examiner considers the "4.7" value to be incorrect, Applicants would appreciate the Examiner's suggestion as to an acceptable value.

Applicants request withdrawal of these three 103(a) rejections.

Claim 10 was rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Ebert, in view of Monte or Cavanak, and Nishizawa et al. (U.S. Patent No. 4,463,024).

Claims 8, 12-16 and 31-37 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Lech, in view of Cavanak and Katsuragi et al. (U.S. Patent No. 5,756,543).

Claims 17 and 18 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Lech in view of Mehta (U.S. Patent No. 5,084,278).

These three rejections are traversed together.

These rejected claims all depend from claim 1. Applicants have argued above that the references do not suggest the desirability of the instant claims. Applicants do not separately argue the patentability of these claims.

Applicants request withdrawal of these three § 103(a) rejections.

CONCLUSION

For the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 1, 4-8, 10, and 1-38) are now in condition for allowance.

In the event the Examiner considers personal contact advantageous to the disposition of this case, she is hereby authorized to call Richard M. Klein, at telephone number 216-363-9000, Cleveland, OH.

Respectfully submitted,

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Sept 23, 2009
Date

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